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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,601	09/24/2003	Aviv Shaish	25727	1529
20529	7590	06/14/2006	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 06/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,601

Applicant(s)

SHAISH ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 11-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group I, Claims 1 and 3-10, in the reply filed on March 6, 2006 is acknowledged.

Claims 1 and 3-10 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "crude Dunaliella powder" in Claims 1 and 9 is a relative term which renders the claim indefinite. The term " crude Dunaliella powder " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The lack of clarity renders the claims vague and ambiguous.

Claim 9 recites the limitation "wherein said Dunaliella" in line 1. There is a lack of clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by adding powder after "Dunaliella" in line 1 of Claim 9; and adding obtained from after "Dunaliella bardawil" in line 2 of Claim 9.

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All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 8 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Hayashi et al. (N, translation of foreign patent provided herein).

Applicant claims a method for reducing insulin and/or glucose plasma level(s) in a subject afflicted with diabetes comprising administering to the subject an effective amount of crude Dunaliella powder, thereby reducing the subject's plasma insulin and/or glucose plasma level(s). Applicant further claims the method according to claim 1, wherein the crude Dunaliella powder is administered orally; wherein the Dunaliella is Dunaliella bardawil.

Hayashi teaches a method of treating diabetes comprising orally administering an effective amount of crude Dunaliella powder to a subject in need thereof, wherein the administering of effective amounts of the algae powder reduced glucose plasma levels in the subject.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. (N) in view of Takenaka et al. (O, translation of foreign language patent provided herein) and (U).

Applicant's claimed invention of Claims 1, 8 and 9 was set forth above. Applicant further claims the method according to claim 1, wherein the powder is encapsulated.

The teachings of Hayashi were set forth above. Hayashi teaches the instantly claimed invention except for wherein the powder is encapsulated. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and at the time the invention was made it was known in the art that the encapsulation of crude Dunaliella powder was useful as a vehicle for the delivery of the claim-designated ingredient to patients in need thereof of therapeutic treatment requiring the oral administration of Dunaliella powder, as evidenced by the teachings of Takenaka and Levy. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the method taught by Hayashi by encapsulating the Dunaliella powder used in the method of treatment taught by Hayashi to provide the instantly claimed invention because Takenaka taught that the encapsulation of Dunaliella powdered extracts

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protects the unstable nutrient from decomposition by light and from degeneration by oxidation, and; Levy taught that the encapsulation of *Dunaliella* provides a convenient vehicle for oral administration of the claim-designated ingredient to patients in need of therapeutic regimens requiring dose amounts of *Dunaliella bardawil*, such as disease conditions associated with diabetes. Thus, the claimed invention would have been merely a matter of judicial selection to one practicing the invention the invention to pick and choose the form for the oral administration of the referenced algal composition to effect a result effect variable for the treatment of diabetes, since at the time the invention was made Hayashi taught that the oral administration of effective amounts of a powdered *Dunaliella bardawil* reduced glucose plasma levels in a diabetic subject in need of treatment of diabetes, and given that Takenaka and Levy taught that the oral administration of the claim-designated algal composition in an encapsulated form was conventional and well known in the art.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. (N), Takenaka et al. (O) and Levy (U) in view Beck (A), Pan et al. (B), Heyman et al. (C) and Smith (P).

Applicant's claimed invention of Claims 1 and 8-10 was set forth above.

Applicant further claims a method according to claim 1, wherein said crude *Dunaliella*

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powder is administered together with one or more activators of nuclear receptors.

Applicant further claims the method of claim 3, wherein the activators of nuclear receptors are peroxisome proliferator-activated receptor α or γ (PPAR α or PPAR γ) agonists. Applicant further claims the method according to claim 4, wherein the PPAR α or PPAR γ agonists are selected from fibrates and thiazolidinediones. Applicant further claims the method according to Claim 5, wherein the fibrates are selected from clofibrate, fenofibrate, bezafibrate, ciprofibrate, beclofibrate and gemfibrozil. Applicant further claims the method according to Claim 5, wherein the thiazolidinediones are selected from AVANDIA™, troglitazone, BRL 49653, pioglitazone, ciglitazone, WAY-120,744, englitazone, AD 5075, darglitazone and rosiglitazone.

The combined teachings of Hayashi, Takenaka and Levy are set forth above. The obvious teachings of Hayashi, Takenaka and Levy teach the instantly claimed invention except for wherein the crude Dunaliella powder is administered together with one or more activators of nuclear receptors. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the method taught by the combined teachings of Hayashi, Takenaka and Levy to provide the instantly claimed invention because at the time the invention was made the instantly claimed activators of nuclear receptors were known in the art for their beneficial functional effect for treating diabetes, as evidenced by the teachings of Beck, Pan, Heyman and Smith. Firstly, Beck teaches a method for the treatment of normolipidaemic diabetes mellitus comprising orally administering an effective amount of bezafibrate. Secondly, Pan teaches a method of reducing the risk of or treating

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diabetes mellitus comprising administering an effective amount of an antihyperlipoproteinemic agent, *e.g.*, fenofibrate, gemfibrozil, clofibrate, bezafibrate, ciprofibrate and clonofibrate in combination with a cholesterol lowering drug, ACE inhibitor, in Column 9, lines 32-58. For example, in Column 15, line 58 to Column 16, line 2, Pan teaches administering gemfibrozil capsules either alone in combination with a cholesterol lowering drug, ACE inhibitor in the treatment of diabetes mellitus. Thirdly, Heyman teaches a method of treating diabetes mellitus comprising administering an effective amount of a thiazolidinedione, *e.g.*, troglitazone, BRL 49653, pioglitazone, ciglitazone, WAY-120,744, englitazone, AD 5075, and darglitazone, in combination with an RXR agonist to a subject. Fourthly, Smith teaches a method of treating diabetes mellitus comprising administering rosiglitazone. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the ingredients taught by Beck, Pan, Heyman and Smith to the method of treatment taught by the obvious teachings of Hayashi, Takenaka and Levy to provide the instantly claimed invention because Beck teaches that the oral administration of bezafibrate reduces the insulin level in normolipidaemic patients suffering from diabetes mellitus; Pan teaches that his method reduces or prevents the onset of diabetes mellitus and the onset of atherosclerosis in mammals, in Column 4, lines 27-34; and, in Column, 2, lines 5-11, Heyman teaches that the combination of an RXR agonist and a PPAR γ agonist, *i.e.*, a thiazolidinedione, achieves synergistic action of the RXR/ PPAR γ heterodimers so as to enhance adipogenic and antidiabetic effects of PPAR γ ; and, Smith teaches that his method for treating diabetes

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mellitus comprising administering rosiglitazone provides a beneficial effect on glycaemic control, on page 1, lines 19-22.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add any of the claimed ingredients taught by either Beck, Pan, Heyman or Smith to encapsulated Dunaliella bardawil used in the method taught by the combined teachings of Hayashi, Takenaka and Levy to provide the claimed method because the claimed invention is no more than the combining of well known ingredients used in well known methods for treating diabetes in a subject in need thereof.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source,

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all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
June 10, 2006